

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Lars Christian RONN et al.

Serial No.: 09/787,443

Group Art Unit: 1647

Filed: July 30, 2001

Examiner: NICHOLS, Christopher J.

For NCAM BINDING COMPOUNDS

**RESPONSE
TO RESTRICTION REQUIREMENT**

Commissioner of Patents
United States Patent and Trademark Office
Washington, D.C. 20231

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Sir:

This paper responds to the Office Action (restriction requirement) mailed January 14, 2003.

Pursuant to the restriction requirement under 35 USC 121 and 372, applicants elect to prosecute the invention of Group I, claims 56-66 and 70-73, drawn to a compound comprising SEQ ID NO:1, with traverse. Traverse is maintained because the restriction requirement fails to apply the standards for determining unity of invention in accordance with PCT Rule 13. When PCT Rule 13 is correctly applied, unity of invention is readily apparent for all of the pending claims, i.e., claims 56-97

MPEP 1850 governs restriction practice for PCT international and national stage applications. MPEP 1850 reads in pertinent part (*emphasis added*):

THE REQUIREMENT FOR "UNITY OF INVENTION "

... when the Office considers international applications ... during the national stage ... PCT Rules 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C.111. ...

Therefore, when the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C.371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C.111. No change was made in restriction practice in United States national applications filed under 35 U.S.C.111 outside the PCT.

In applying PCT Rule 13.2 to . . . national stage applications under 35 U.S.C.371, examiners should consider for unity of invention all the claims to different categories . . . which meet the requirements of PCT Rule 13.2. . . . Those categories . . . now appear as a part of Annex B to the Administrative Instructions . . . with a statement describing the method for determining whether the requirement of unity of invention is satisfied. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "*special technical features*" is defined as meaning *those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.* . . . Annex B also contains examples concerning unity of invention.

A. Independent and Dependent Claims

Unity of invention has to be considered in the first place only in relation to the independent claims . . . and not the dependent claims . . . in the same category of claim. . . . If the independent claims avoid the prior art and satisfy the requirement of unity of invention, *no problem of lack of unity arises in respect of any claims that depend on the independent claims.* . . . Moreover, *no problem arises in the case of a combination/subcombination situation* where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination. . . .

D. "Markush Practice "

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(C)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives " refer to cases where the compounds share a common

chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together.

In paragraph (C)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

MPEP 1850 is in line with the decision in *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, 231 USPQ 590 (E. D. Va. 1986).

PCT Rules 13.2 and 13.2 read in pertinent part (*emphasis added*):

13.1 Requirement

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

13.2 Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

... the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving *one or more* of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features *that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.*

As set forth in Annex B, the relationship between independent and dependent claims is established.

(c) Independent and Dependent Claims.

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

(ii) If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

(iii) This method for determining whether unity of invention exists is intended to be applied even before the commencement of the international search. Where a search of the prior art is made, an initial determination of unity of invention, based on the assumption that the claims avoid the prior art, may be reconsidered on the basis of the results of the search of the prior art.

Applying the foregoing standards to the present situation readily demonstrates how unity of invention among invention Groups 1-18 is readily satisfied and, moreover, how the restriction requirement of record incorrectly applies these standards.

Unity of invention is, first, decided in connection with independent claims, only; if unity of invention is satisfied for the independent claims, and the independent claims turn out to be allowable over the prior art, no restriction can be made between dependent claims or between dependent claims, on the one hand, in the corresponding independent claims, on the other. MPEP 1805. In the instant case, independent claim 56 satisfies the requirements for unity of invention, and no determination of unpatentability in connection with independent claim 56 has been made.

In accordance with MPEP 1805 and Appendix B of the PCT Rules, present claim 56 falls within the scope of so called Markush practice, i.e., "were a single claim defines alternatives

(chemical or non-chemical)". Annex B, (f). Examples 18 and 19 of Annex B illustrates how the presently claimed invention satisfies the requirements for unity of invention.

Example 18

... The compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen.

In this case the indolyl moiety is the significant structural element which is shared by all of the alternatives. Since all the claimed compounds are alleged to possess the same utility, unity is present.

Example 19

... The compounds are alleged to be useful as pharmaceuticals for relieving lower back pain. In this particular case the iminothioether group $N=C-SCH_3$ linked to a six atom ring is the significant structural element which is shared by all the alternatives. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

In accordance with independent claim 56, all sequences falling within the scope of the claim contain a maximum of 12 amino acids residues, with every alternative sequence having structural element "K-R" in common. Since all of the sequences within the scope of the claim are alleged to have the same utility, i.e., stimulating or promoting neurite outgrowth from NCAM presenting cells and/or proliferation thereof. Therefore, unity of invention is established for independent claim 56 together with all claims dependent, thereon, i.e., claims 57-97.

In that the restriction requirement merely states that the sequence "recite a particular technical feature" (whatever this is intended to mean), merely begs the question of what, in fact, the technical feature, allegedly, is. As explained, above, at least one technical feature is shared by all the claims.

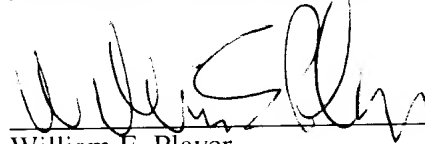
Applicants also wish mention a decision (No. 2000-03-24, copy attached) by the Swedish Patent and Registration Office (PRV) during the international stage of the subject application in connection with unity of invention. Following applicant's protest against an objection to unity of invention, PRV Board decided that the claims did, indeed, comply with the requirements for unity of invention. This decision, of course, is not controlling legal precedent in the present case. It is submitted merely for the Examiner's consideration.

Favorable action is requested.

Respectfully submitted,

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Decision by the Board established according to PCT Rule 40.2(c)**Protest against payment of an additional search fee for novelty search in the international application PCT/DK99/00500.**

The examiner has invited the applicant to pay three additional search fees since it is considered that claims 1-9, that are the unifying link between the claims, do not fulfil the requirements of novelty and inventive step. The claims are divided into four different inventions, namely:

Invention No 1: Claims 12-30, a peptide that comprises at least 2 basic amino acid residues within a sequence of 10 amino acids.

Invention No 2: Claims 31-40, a peptide which comprises at least 2 basic amino acid residues and at least 1 apolar amino acid.

Invention No 3: Claims 27-30, 41-44 and 55-58, a non-peptide, which binds to the Ig1 or Ig2 domains.

Invention No 4: Claims 45-54 a peptide which comprises at least 2 acidic amino acid residues and at least 1 apolar amino acid.

The applicant has under protest paid three additional search fees for invention 2-4.

A reasoned statement accompanied the payment, cf. PCT Rule 40.2 (c).

The decision of the Board is that the claims do comply with the requirements of unity of invention for the following reasons.

According to PCT Rule 13.1, an application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept.

According to PCT Rule 13.2, the requirement of unity of invention is fulfilled only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical feature. The special technical features shall also define a contribution which the claimed inventions, considered as a whole, makes over the prior art.

The special technical feature relates to compounds, which binds to the NCAM Ig1-Ig2 domains and is capable of stimulating or promoting neurite outgrowth from NCAM presenting cells and/or proliferation thereof.

The cited prior art document WO 9632959 relates to a method for promoting neural growth *in vivo* in the central nervous system of a mammal comprising administering to said mammal a

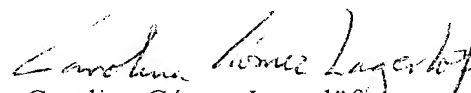
neural promoting amount of an agent, said agent comprising a neural cell adhesion molecule. It is not specifically stated that this agent binds to the NCAM Ig1-Ig2 domains. It is only stated that this agent may be selected from any cell adhesion molecule, which are capable of modulating or promoting CNS neurite outgrowth. One of the preferred molecules is NCAM. It is further stated that it can be a fragment of these molecules and one of the preferred structural motifs is Ig1-Ig2. The possibility that the domains of NCAM per se should possess the property of being capable of promoting neurite outgrowth is not mentioned. NCAM is one of the mentioned molecules, but it is not represented in the experimental part of the document.

Claims 1-9 are considered to fulfil the requirements of novelty and inventive step. Consequently the claimed invention complies with the requirements for unity of invention according to PCT Rule 13.2.

The Board orders the reimbursement of the paid three additional fees.

The Board has consisted of Mr. J.-E. Bodin, Deputy Head, Patents, Ms. E. Johansson, Senior Examiner, Patent Expert, Ms. I. Söderlund, Legal Adviser and Ms. C. Gómez Lagerlöf, Examiner and Referent.


Jan- Eric Bodin


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